Delivering Efficiency to Healthcare

FAX COVER

From: *National Distribution & Contracting, Inc.* *Djana Milliken – Compliance* ***URGENT*** ****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.**** **To:** *Purchasing or Regulations Department*	**Date:** *9/15/2016*
Pages: *5* *(Including cover page)*	
Regarding: *Leonhard Lang* *Defibrillation Electrode SKINTACT Item # DF29N*	

Comments:

Dear Distributor,

Attached is a letter we received from Leonhard Lang regarding the recall on item # DF29N. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. ***Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Djana Milliken

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-366-3225 / Fax: 615.229-68015

LEONHARD LANG
Connect with Quality

From:

Leonhard Lang USA
PO Box 1951
Inverness, FL 34451

September 12, 2016

IMPORTANT SAFETY NOTICE FOR FINAL CUSTOMERS

Reference: CAP-16-0078

Product trade name: Defibrillation Electrode SKINTACT DF29N

Required action: Destruction of affected products

Target group: Final Customers

Dear Ladies and Gentlemen,

This letter is to inform you of the recall of the article listed below:

- **50028 Defibrillation Electrode SKINTACT DF29N**

You will be informed by your supplier about affected lot numbers and quantities delivered to you. A description of how to identify the lot number on the product packaging is attached (see annex).

Please read this letter carefully and follow the steps in section 2 of this letter.

1. Description of the defect

Summary: During an investigation triggered by customer feedback, it was discovered that it can be aggravated to connect these defibrillation electrodes with the defibrillator Welch Allyn AED 10. As a consequence, it may happen that the user does not connect the electrodes with the defibrillator in an emergency situation.

Conditions for the occurrence of the issue: Use of defibrillation electrodes DF29N with the defibrillator Welch Allyn AED 10.

Potential risk: There is a risk that these electrodes will be connected with the defibrillator only with delay or not at all. This may cause a situation in which a patient who is in a life-threatening condition and requires a defibrillation shock, cannot be treated in good time.

Safety information: With this letter, Leonhard Lang informs you of the fact that this safety notices will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to comply with the requirements of this recall action.

2. Actions and timeframe of the recall

a) Please make sure that within your organization all users of the products listed above and any other persons requiring this information receive this important safety notice.

b) Make sure all defibrillation electrodes DF29N you have received and not yet used are secured and destroyed. Confirm the disposition of the products (consumed/destroyed) by completing the form "Confirmation of Destruction / Consumption" (see annex), sign it and send it to your supplier not later than **October 14, 2016**.

Please keep the signed "Confirmation of Destruction / Consumption" form at least until your supplier informs you of the termination of this recall.

LEONHARD LANG
Connect with Quality

3. Compensation for the recalled electrodes

There will not be any replacement electrodes compatible with Welch Allyn defibrillators as Leonhard Lang will discontinue the distribution of model DF29N in your market. Please contact your supplier for compensation.

For the termination of the recall it is necessary that you confirm in writing the destruction of all electrodes that were not consumed. Compensation and replacement products will be provided on the basis of the data provided by you in the completed "Confirmation of Destruction / Consumption" form.

For processing compensation, please get in touch with your supplier.

We apologize for any inconvenience caused by this issue. However, to allow patients and users to safely utilize our products, these measures have to be taken immediately. We assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact our sales staff with any questions you may have.

Yours sincerely,

Ross Cooper
President, LLUSA
Tel: 800-903-6199
Fax: 352-344-0870
E-mail: ross.cooper@leonhardlangusa.com

List of annexes:

- Identification of the Lot Number on Product Packaging
- Form "Confirmation of Destruction / Consumption"

LEONHARD LANG
Connect with Quality

Recall CAP-16-00078

Lot Number Identification on the Product-Packaging

An example of a defibrillation electrode affected by the recall is shown below:

The lot number is always preceded by the following symbol: LOT

For your reference, we have marked the lot number in this example with a red frame.